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(54) Title: VARIABLE STIFFNESS ANGIOPLASTY GUIDEWIRE

(57) Abstract

An angioplasty guidewire includes a proximal shaft formed with an axial passage and a variable stiffness intermediate section extending axially from the tubular shaft and having a corridor aligned axially with the passage and terminating at a distal joint. The intermediate section comprises a plurality of stiffening elements. A core element is slidably disposed axially through the passage and includes a distal end projecting into the corridor and attached to the distal joint while a flexible distal tip is mounted to the end of the intermediate portion and projects axially therefrom.

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VARIABLE STIFFNESS ANGIOPLASTY GUIDEWIRE

This application is a continuation-in-part of pending U.S. Patent Application Serial No. 08/879,569, filed June 20, 1997.

Field of the Invention

The invention relates to guidewires used in angioplasty procedures and more particularly an angioplasty guidewire having shiftable control elements to provide a variable stiffness capability.

Background of the Invention

Treatments for cardiovascular conditions caused by restricted or blocked blood vessels increasingly involve trauma minimizing non-invasive surgical techniques. For example, in an angioplasty procedure, an elongated and relatively thin catheter can treat a blood vessel restriction, commonly referred to as a stenosis or occlusion, by advancing through the vessel to a location proximate the restriction. A balloon disposed distally on the end of the catheter radially expands against the restriction to open the vessel for increased bloodflow. However, because many angioplasty catheters comprise "over the wire" designs, in order for the catheter to reach the stenosed location, a guidewire typically must first define the vascular path.

Conventional angioplasty guidewires typically include a proximal

shaft comprising a solid wire or a solid wall tube with an outer diameter equal to the nominal size of the guidewire. The shaft primarily functions to guide and support a catheter, and to smoothly transmit rotation from the proximal end to an intermediate section. The intermediate section extends axially from the proximal shaft and generally comprises a tapered core wire surrounded by a coiled spring and typically has more flexibility than the proximal shaft. Like the proximal shaft, the intermediate section must assist in guiding the catheter and smoothly transmitting rotation. However, some degree of flexibility in the intermediate section is desirable to conform the catheter to the curvature of the aortic arch and the coronary arteries. Extending from the intermediate section at a distal joint is a flexible distal tip that accepts a pre-formed curved shape resembling a "J". The curved tip tends to steer the guidewire in the direction of the hook.

To reach a blood vessel restriction, conventional guidewires typically traverse tortuous paths having relatively sharp turns and passage constrictions. A common technique to aid in steering the guidewire, especially where the path branches into a plurality of passages, involves rotating the shaft to redirect the pre-formed "J" towards a particular branch, then advancing the wire once the correct orientation is achieved. Unfortunately, as the wire advances into blood vessels of reduced diameter, the friction generated between the guidewire and the inner walls of the vessel tends to inhibit rotation from the proximal shaft, through the intermediate section to the distal tip. Consequently, overly flexible intermediate sections are susceptible to substantial twisting and doubling over, thereby failing to transmit the desired rotation to the distal end of the guidewire.

Another problem faced by conventional guidewires involves supporting the catheter once the correct position is reached. On occasion, after the guidewire is positioned, an exchange is made whereby the relatively flexible shaft is replaced by a relatively stiff shaft with the catheter remaining in place. Although conventionally exchanging wires is a commonplace practice, the procedure undesirably adds steps in the overall procedure, and exposes the

insertion area to potential contamination.

One proposal for providing an angioplasty guidewire with a controllably variable stiffness is disclosed in U.S. Patent No. 4,676,249 to Arenas. The guidewire includes an elongated core wire and a tubular stiffening member movable within the lumen of a flexible coiled wire body defining a distal end of the guidewire. Varying degrees of flexibility are possible at the distal end by shifting the relative positions of the core wire and/or the tubular stiffening member in the wire body. U.S. Patent No. 4,873,983 to Winters teaches a similar device that includes a tapered core wire moveable within the distal end of an outer tube to steer the distal end of the tube through a vasculature.

In both the Arenas and Winters devices, the respective stiffening features affect only the distal ends of the guidewires. Thus, support in the intermediate section of the guidewire, for example, to assist tracking of a stent catheter, is unavailable. A further disadvantage of the above-described devices involves the lack of torsional support provided by the stiffening member to ensure full rotational transmission through the wires to effect proper steering in relatively constrained blood vessels.

Another approach, disclosed in U.S. Patent No. 5,542,434 to Imran, involves a guidewire having a core wire and a hypotube coaxially disposed around the core wire. An actuator wire formed of a memory material runs longitudinally with the core wire at the distal end of the guidewire to stiffen in response to thermal energy supplied by a heater. The core wire and hypotube are bonded together by an adhesive to prevent relative axial or torsional displacement.

While the Imran device provides a relatively stiff guidewire for purposes of torque control, such stiffness at the proximal and intermediate sections of the guidewire is permanent, and not selectively controllable. Thus, like the Arenas and Winters devices described above, the variable stiffening feature is limited to the distal end of the guidewire. Moreover, the stiffness is controllable only through use of a relatively complex and costly thermal mechanism requiring

additional wires running the length of the guidewire.

Therefore, the need exists for an angioplasty guidewire having controllable elements that cooperate to provide a variable stiffness in the intermediate section of the guidewire. Moreover, the need also exists for such a guidewire having a selective locking mechanism to provide enhanced torsional control during insertion of the catheter through a vasculature. The guidewire of the present invention satisfies these needs.

SUMMARY OF THE INVENTION

The guidewire and method of the present invention provides the capability of controllably changing the stiffness of the intermediate section while the guidewire remains in vivo. This eliminates the need to exchange guidewire elements when added support is necessary for particular procedures to enhance catheter tracking. Moreover, the elements may be locked in some circumstances or splined to maximize torsional transmission during advancement of the guidewire through constricted vascular passages.

To realize the above advantages, the present invention, in one form, comprises an angioplasty guidewire including a proximal shaft formed with an axial passage and a variable stiffness intermediate section extending axially from the tubular shaft and having a corridor aligned axially with the passage and terminating at a distal joint. The intermediate section comprises a plurality of stiffening elements. A core element is slidably disposed axially through the passage and includes a distal end projecting into the corridor and attached to the distal joint while a flexible distal tip is mounted to the end of the intermediate portion and projects axially therefrom.

In another form, the invention comprises an angioplasty catheter system including an angioplasty catheter having an expandable element for dilating radially outwardly inside a blood vessel and a controllably variable guidewire. The guidewire includes a proximal tubular shaft formed with an axial passage and

a variable stiffness intermediate section extending axially from the tubular shaft and having a corridor aligned axially with the passage and terminating at a distal joint. The intermediate section comprises a plurality of stiffening elements. The guidewire further includes a core element slidably disposed axially through the passage and having a distal end projecting into the corridor and attached to the distal joint. A flexible distal tip is mounted to the end of the intermediate portion and projects axially therefrom.

In yet another form, the invention comprises a method of deploying a guidewire through a vasculature to a restricted location in a blood vessel. The guidewire includes a proximal shaft, an intermediate section having a plurality of stiffening elements and projecting axially from the shaft, and a core element slidably disposed inside the shaft and attached to a distal end of the intermediate section. The method includes the steps of first shifting the core element into an initial position within the intermediate section of the guidewire to effect a predetermined flexibility in the intermediate section; inserting the guidewire through an incision accessing the vasculature;
threading the guidewire through the vasculature to the restricted location; and stiffening the intermediate section by axially displacing the core element to actuate at least one of the stiffening elements and provide sufficient stiffness to track a catheter apparatus.

Other features and advantages of the present invention will be apparent from the following detailed description when read in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a partial diagrammatical view of a catheter system according to one embodiment of the present invention;

FIG. 2 is a partial longitudinal sectional view of a guidewire according to a first embodiment of the present invention;

FIG. 3 is a partial longitudinal sectional view similar to FIG. 2;

FIG. 4 is a partial longitudinal sectional view of a guidewire according to a second embodiment of the present invention;

FIG. 5 is a partial longitudinal sectional view similar to FIG. 4;

FIG. 6 is a partial longitudinal sectional view of a guidewire according to a third embodiment of the present invention;

FIG. 7 is an axial cross sectional view along lines 7-7 of FIG. 6;

FIG. 8 is a partial longitudinal sectional view of a guidewire according to a fourth embodiment of the present invention;

FIG. 9 is a partial longitudinal sectional view similar to FIG. 8;

FIG. 10 is a partial longitudinal sectional view of a guidewire according to a fifth embodiment;

FIG. 11 is a partial enlarged axial sectional view of the distal joint of Figure 10;

FIG. 12 is a cross-sectional view along lines 12-12 of Figure 11;

FIG. 13 is a partial enlarged axial sectional view of the intermediate section-proximal shaft joint of Figure 10;

FIG. 14 is a cross-sectional view along lines 14-14 of Figure 13; and

FIGS. 15-20 are partial longitudinal sectional views of alternative stiffener element arrangements for the embodiment of Figure 10.

DETAILED DESCRIPTION OF THE INVENTION

Angioplasty catheter systems and procedures enable operators to perform life-saving treatments with minimal tissue trauma experienced by the patient. Referring now to Figure 1, an angioplasty catheter 10 of the "over the wire" design having a radially expandable balloon 12 is shown positioned within a branch blood vessel 14. From the point of entry, typically an incision made at 16, to the eventual destination 18, the catheter must traverse a winding, branch laden

path. As a result, the catheter must rely on a relatively flexible guidewire to establish the path for the catheter to track.

Referring now to Figures 2 and 3, a guidewire in accordance with a first embodiment of the present invention, generally designated 20, provides variable stiffness capability in vivo and includes a flexible member 30 moveable relative to a stiffener 40 that longitudinally extends along respective guidewire segments defining a proximal shaft 22, an intermediate section 24, and a distal portion 26.

The flexible member 30 comprises a core wire formed of a relatively flexible strand of stainless steel measuring about 180 centimeters and having a relatively constant diameter over a majority of its length. Typically, the diameter ranges from about 0.005 inches to 0.01 inches, depending upon the application involved. Respective primary and secondary tapers 32 and 34 are formed in the core wire along the intermediate section to narrow the core wire and provide added flexibility. A distal end 36 of the core wire terminates in a bonded distal joint 38 that connects the intermediate section 24 the distal portion 26 of the guidewire.

With continuing reference to Figures 2 and 3, the stiffener 40 comprises a formed hypotube that coaxially extends longitudinally along the core wire 30 in slidable relationship therewith. The hypotube is formed with a relatively stiff shaft section 42 that narrows down, at 44, to define a shoulder 46 for mounting one end of an intermediate spring 48. The other end of the spring projects axially beyond the distal joint 38 and defines an inner spring 54 that terminates at a distal tip 58. The narrowed section of the hypotube provides somewhat more flexibility than the stiff shaft section and tapers radially inwardly at 50 to form a restricted mouth 52 for complementally engaging the core wire secondary taper 34. The mouth and the secondary taper cooperate to form an axially and radially inhibiting friction fit.

The proximal shaft 22 and the intermediate section 24 together

comprise various lengths of the core wire 30 and the hypotube 40. However, for convention purposes, the intermediate spring 48 typically defines the guidewire intermediate section. Thus, under this convention, the proximal shaft 22 extends from the proximal end of the guidewire (not shown), to the annular shoulder 46 formed in the slidable hypotube 40.

Further referring to Figure 2, the distal portion 26 extends axially from the distal joint 38 and includes respective inner and outer coil springs 54 and 56 disposed concentrically and interposed between the distal joint 38 and the distal tip 58. The tip typically retains a pre-formed "J" shape (not shown) to urge the guidewire in desired directions and thereby assist in steering the catheter during insertion through the vasculature.

Assembly of the guidewire 20 is well within the level of skill in the art, and generally includes first sliding the core wire 30 through the length of the hypotube 40 until the restricted mouth 34 frictionally engages the secondary taper 34. The intermediate spring 48 is then run over the uncovered portion of the core wire projecting outwardly from the distal tip of the hypotube and attached to the annular shoulder 46 with a suitable adhesive. The distal joint 38 is then formed at the tip of the core wire 30 to confine the intermediate spring therearound with a globule of solder material or the like. With the inner spring 54 projecting axially from the intermediate spring, the outer spring 56 is slid coaxially over the inner spring and then bonded to the distal joint with adhesive. Next, the opposite ends of the springs are capped by mounting the hemispherical tip 58. Following assembly, the guidewire is typically packaged separately in a sterile container for use in an angioplasty catheter system.

Referring now to Figures 1, 2 and 3, during operation, the guidewire 20 is typically first removed from its sterile packaging and inserted into the vascular system through the small external incision 16. Initial advancement of the guidewire through the body requires a relatively high degree of flexibility at the distal portion 26 of the guidewire, with a moderate level of flexibility at the

intermediate section 24. To maximize available flexibility at the distal portion, the hypotube 40 conveniently frictionally locks to the core wire 30 by sliding the hypotube rearwardly to engage the complementally formed mouth 52 and secondary taper 34.

Locking of the core wire 30 to the hypotube 40 also serves to maximize the transmission of torque from the proximal end 22 of the guidewire to the intermediate section 24 by integrating the core wire and hypotube into a relatively large diameter rod, rather than a substantially thin wire. Those skilled in the art will appreciate this feature to substantially assist the operator in steering the guidewire 20 through the vasculature.

For example, as shown in Figure 1, a typical path for the guidewire 20 to traverse often includes sharp turns such as at 60, and branch points leading to a plurality of branch paths, such as at 62 and 64. The guidewire may be conveniently steered and threaded along the path by rotating the entire assembly to orient the pre-formed "J" (not shown) such that the hook points in a desired direction. However, as the blood vessels become more constrained, rotation of the guidewire along the 180 centimeter length becomes more difficult, and even stops altogether unless the proximal, intermediate and distal portions have a relatively high torsional stiffness. Under such circumstances, the operator merely locks the hypotube 40 and the core wire 30 together to achieve the added torsional stiffness necessary to permit rotation of the guidewire in constrained areas.

Once the guidewire 20 is successfully threaded in position, the operator may then choose to stiffen the intermediate section 24 by sliding the hypotube 40 distally to provide axial support near the treatment area. Advancement of the hypotube distally along the core wire, as shown in Figure 3, compresses the intermediate spring while bringing more of the relatively stiff shaft section of the hypotube into the intermediate section of the guidewire. The net result is a cooperative stiffening of the intermediate section by the interaction of the hypotube with the core wire. With the added axial support, the balloon or

stent catheter 10 may track the guidewire 20 and treat the location without undesirable overflexing at the intermediate section of the guidewire. Following the treatment, the hypotube may be shifted back to its initially locked position to enable swift withdrawal of the guidewire from the body.

Referring now to Figures 4 and 5, a guidewire in accordance with a second embodiment of the present invention, generally designated 70, is formed substantially similar to the first embodiment albeit with a modified core wire 72 construction. The core wire includes a sawtooth wave-shaped diametrically offset portion 74 disposed between a secondary barrel 73 and a secondary taper 75. The offset portion provides a friction fit when engaged with an internal radial surface 76 in a hypotube 80.

In operation, the guidewire 70 functions in much the same manner as the first embodiment, but provides a locking friction fit over a greater range of hypotube positions. Figure 4 illustrates a locked position, while the stiffening action of the hypotube shifted axially is shown in Figure 5.

Referring now to Figures 6 and 7, in yet another embodiment, a guidewire 81 is formed substantially similar to the aforedescribed embodiments albeit with a modified core wire/hypotube construction. The guidewire includes a core wire 82 formed with a polygonal cross-section, such as a hexagonal or pentagonal shape. An inner surface 84 of a hypotube 86 is complementally formed with the same polygonal shape to axially receive the formed core wire.

Operation of the modified core wire/hypotube embodiment is also similar to the previously described embodiments. However, unlike the prior constructions, which included a selectively engageable locking mechanism to effect enhanced torsional stiffness, the modified construction provides continuous torsional support. During positional maneuvering of the guidewire, rotation of the hypotube 86 rotates the inner wire 82 due to the complementally formed polygonal surfaces thereby transmitting any applied torque from the proximal end to the tip and directing the J-shaped tip into the desired branch of the artery.

With reference to Figures 8 and 9, a guidewire in accordance with a fourth embodiment of the present invention, and generally designated 100, includes a stiffener 110 slidably received within a closed ended flexible member 120 that longitudinally extends along respective segments defining a proximal shaft 102, an intermediate section 104, and a distal portion 106.

The stiffener 110 comprises a core wire formed of an elongated thin rod of tungsten/stainless steel alloy having a diameter within the range of 0.004 inches to 0.009 inches and a length of approximately 180 centimeters. Unlike the first and second embodiments, the core wire diameter remains constant with the distal tip truncated in a flat engagement end 112.

Further referring to Figure 8, the flexible member 120 comprises a formed hypotube including a relatively flexible tubular body formed with an interior blind bore 122 having a constant internal diameter to slidably receive the core wire 110 and a distal wall 124 to serve as a stop. The exterior of the hypotube includes a major diameter 126 extending most of the hypotube length. The major diameter narrows at 128 along a secondary taper 130 and ends in a secondary barrel 132. The secondary barrel extends longitudinally to 134 where it begins to fall off in a primary taper 136 that extends to a primary barrel 138. The end of the hypotube is swaged down into a tapered section 140 that bonds to a distal joint 142.

With further reference to Figure 8, an intermediate spring 144 receives the hypotube 120 and bonds to the secondary taper 130 through the use of a suitable adhesive that forms an adhesive joint 146. The opposite end of the spring connects to the distal joint 142. Unlike the first and second embodiments, the intermediate spring 144 lies mounted in an axially fixed position.

The distal portion 106 is formed substantially similar to the first and second embodiments. An inner spring 148 is formed integrally with the intermediate spring and projects axially distally. The inner spring tapers radially inwardly and then forms a constant diameter in an axially expanded configuration

to provide a larger pitch. An outer spring 150 coaxially confines the inner spring and bonds with the inner spring to the distal point 142. A hemispherical cap 152 bonds to the ends of the springs.

Assembly of the guidewire 100 involves first inserting the intermediate spring 144 over the distal end of the hypotube 120 and bonding one end of the spring to the secondary taper at 154. The other end of the spring is then bonded or soldered to the distal joint 142, along with the distal end of the hypotube itself, and the respective inner and outer springs 148 and 150. The cap 152 is then attached to the opposite end of the springs and pre-formed with the springs to take on a "J"-shape (not shown). The core wire 110 is then inserted through the length of the hypotube.

Referring to Figures 8 and 9, during operation, the guidewire 100 is initially inserted into the vasculature with the core wire 110 somewhat retracted from the end of the hypotube 120 to maximize the flexibility of the assembly during advancement along winding vessels. In relatively constricted areas where turns must be artfully negotiated, the operator merely rotates the hypotube shaft to effect a corresponding rotation at the distal portion 106, thereby re-orienting the distal "J", and urging the guidewire along another direction. Because of the relatively large diameter of the hypotube 120, the transmission of rotation of the assembly from the proximal end to the intermediate section is substantially unaffected.

Once positioned at the treatment site, the guidewire stiffness may be increased by conveniently sliding the core wire 110 through the hypotube bore 122 toward the formed stop 124. Advancement of the core wire distally results in a cooperation between the core wire and the hypotube to impart a varying stiffness corresponding to the depth of insertion of the core wire through the hypotube bore 122. Depending upon the application, the guidewire will reflect a level of stiffness necessary to properly support a balloon or stent catheter. When the procedure is completed, the core wire may be removed to restore flexibility to the

guidewire so that it may be quickly removed.

Referring now to Figures 10 through 19, a fifth embodiment of the present invention, generally designated 160, comprises a guidewire having the capability to provide a range of flexibility in the intermediate portion to accept and provide trackability to a wide range of catheter stiffness.

With particular reference to Figure 10, the guidewire 160 incorporates many of the structural features of the first two embodiments, most notably a core wire 162 slidably disposed coaxially within a tubular shaft or hypotube 164 and having a portion 166 that extends axially from the hypotube distal end. The core wire is preferably splined at the joints (Figures 12 and 14) to provide one or more torquable joints.

One of the features included in the fifth embodiment, and not practiced in the aforedescribed embodiments, comprises a multi-element stiffening mechanism comprising a plurality of stiffeners 168 and 170. The stiffeners comprise respective compressible inner and outer coil springs and are mounted to the distal end of the hypotube 164 to project axially therefrom. The stiffening elements are concentrically disposed around the portion of the core wire that projects axially from the end of the hypotube. While Figures 10 through 20 illustrate the outer coil spring with the respective coils in a spaced apart orientation, this is done so merely for purposes of clarity. In practice, the coils are wound to eliminate any spacing therebetween, thereby minimizing any "spongy" effects as a catheter advances along the guidewire.

The respective distal ends of the core wire 162 and inner spring 168 terminate in a distal joint 172 that also attaches to a portion of the outer spring 170. As a result, the inner and outer springs are responsive to slidable movement of the distal joint which responds to action by the core wire. A distal portion 174 of the guidewire projects axially from the distal joint and is constructed substantially similar to the three previously described embodiments.

Unlike the previously described embodiments, the guidewire 160

according to the fifth embodiment incorporates the inner stiffening spring 168 to complement the variable stiffening characteristics of the outer spring 170. This enables further control by the operator over the stiffness capabilities of the guidewire.

Figures 15 through 18 illustrate possible alternatives to stiffeners formed helically from standard cylindrical wire. Such configurations include plastic or metallic wire 173 formed with a kidney shaped cross-section (Figures 15 and 18), and wound in a helical manner, or kidney shaped beads 175 (Figure 16) formed centrally with bores 177 for threading the core wire 162 therethrough. The kidney shape includes a concave surface that complementally engages the convex surface of adjacent wound wire. Also envisioned is an alternating arrangement of spherical and conical bead elements 176 and 178 (Figure 17) to impart the complementary stiffening characteristics.

In operation, the guidewire 160 is introduced into a vasculature in much the same manner as the aforedescribed embodiments. Once the distal end 174 is positioned proximate a predetermined location, often a stenosis or lesion, a lesion treatment device such as a catheter or stent is coupled to the guidewire to track the wire path for guidance to the lesion area. During tracking, the operator can adjust the support provided by the guidewire for the catheter by pulling the core wire proximally to compress the inner stiffening element. This provides proximal and intermediate firmness to successfully track the catheter along the entire length of the guidewire.

Those skilled in the art will appreciate the many benefits and advantages afforded by the present invention. Of significant importance is the controllable axial stiffness feature requiring merely relative axial displacement of the core wire with respect to the hypotube to vary the flexibility of the guidewire in vivo. This feature eliminates the need to effect any exchange in hardware preliminary to the actual stent delivery or balloon expansion step.

The invention also offers an important advantage in allowing the

operator to adjust the torsional stiffness during operation merely by locking the hypotube and core wire together (as in the first and second embodiments), or through the splined construction of the hypotube itself (third and fourth embodiments). Such an advantage permits reliable rotational steering of the guidewire through the vascular system with minimal torsional interference caused by constricted blood vessels and the like.

While the invention has been particularly shown and described with reference to the preferred embodiments thereof, it will be understood by those skilled in the art that various changes in form and detail may be made therein without departing from the spirit and scope of the invention. For example, while the embodiments disclosed above illustrate relative sliding motion between the core wire and hypotube to effect compression of the stiffening elements, it is envisioned, as shown in Figure 19, that a formed piston 180, be slidably disposed along the core wire 162 and placed in axial confronting engagement with the stiffening elements 168 and 170, and hydraulically actuated by introducing non-compressible fluid into the proximal end of the guidewire shaft 164 to compress the elements and impart the variable stiffness feature. Additionally, the inner coil spring may be formed in a canted configuration, as shown in Figure 20, to provide further operational flexibility.

WHAT IS CLAIMED IS:

1. An angioplasty guidewire comprising:
a proximal shaft formed with an axial passage;
a variable stiffness intermediate section extending axially from said tubular shaft and having a corridor aligned axially with said passage and terminating at a distal joint, said intermediate section comprising a plurality of stiffening elements;
a core element slidably disposed axially through said passage and having a distal end projecting into said corridor and attached to said distal joint; and
a flexible distal tip mounted to the end of said intermediate portion and projecting axially therefrom.

2. An angioplasty guidewire according to claim 1 wherein:
said core element distal end is splined atsaid distal joint.

3. An angioplasty guidewire according to claim 1 wherein:
said intermediate section comprises at least one spring element.

4. An angioplasty guidewire according to claim 3 wherein:
said intermediate section comprises a first inner spring and a second outer spring disposed coaxially around said first inner spring.

5. An angioplasty guidewire according to claim 4 wherein:
said first inner spring includes a formed kidney-shaped cross-section having a concave surface for engaging adjacent spring portions.

6. An angioplasty guidewire according to claim 1 wherein:

said plurality of stiffening elements are disposed along said core element distal end; and said guidewire further including

an outer spring positioned in coaxial relationship with said inner elements.

7. An angioplasty guidewire according to claim 6 wherein:

said inner elements are formed substantially spherical with respective concave portions to complementally engage the convex surface of adjacent elements and including respective central bores for receiving said core element.

8. An angioplasty guidewire according to claim 6 wherein:

said inner elements comprising respective spherically formed beads with throughbores for receiving said core element and respective spacers formed with oppositely facing concave recesses to complementally engage respective pairs of spherical beads in interposed relationship.

9. An angioplasty guidewire according to claim 3 wherein:

said at least one spring element comprises an inner spring formed with wire having a kidney-shaped cross-section.

10. An angioplasty guidewire according to claim 1 wherein:

said passage is formed oversize with respect to said core element to receive hydraulic fluid and said guidewire further including an annular piston sealably disposed coaxially between said core element and said tubular shaft and responsive to said hydraulic fluid to alter the stiffness of said intermediate section.

11. An angioplasty catheter system comprising:

an angioplasty catheter having an expandable element for dilating

radially outwardly inside a blood vessel; and a controllably variable guidewire including

a proximal tubular shaft formed with an axial passage;

a variable stiffness intermediate section extending axially from said tubular shaft and having a corridor aligned axially with said passage and terminating at a distal joint, said intermediate section comprising a plurality of stiffening elements;

a core element slidably disposed axially through said passage and having a distal end projecting into said corridor and attached to said distal joint; and

a flexible distal tip mounted to the end of said intermediate portion and projecting axially therefrom.

12. An angioplasty catheter system according to claim 11 wherein:
said expandable element comprises a stent.

13. An angioplasty catheter system according to claim 11 wherein:
said expandable element comprises a balloon.

14. A method of deploying a guidewire through a vasculature to a restricted location in a blood vessel, said guidewire including a proximal shaft, an intermediate section having a plurality of stiffening elements and projecting axially from said shaft, and a core element slidably disposed inside said shaft and attached to a distal end of said intermediate section, said method including the steps of:

shifting said core element into an initial position within said intermediate section of said guidewire to effect a predetermined flexibility in said intermediate section;

inserting said guidewire through an incision accessing said vasculature;

threading said guidewire through said vasculature to said restricted location; and

stiffening said intermediate section by axially displacing said core element to actuate at least one of said stiffening elements and provide sufficient stiffness to track a catheter apparatus.

15. A method according to claim 14 wherein said core element includes a piston ring sealably disposed coaxially between said core element and said shaft; and

said stiffening step includes hydraulically actuating said piston ring to actuate said stiffening elements.

16. An angioplasty guidewire comprising:

a proximal shaft having a distel end;

an intermediate section extending axially outwardly from said shaft distal end to a distal joint and including a stiffener and a flexible member, said stiffener and flexible member disposed in coaxial slidable relationship and operable, when said stiffener and flexible member undergo relative axial shifting, to cooperatively impart a variable stiffening force on said intermediate section; and

a flexible distal tip mounted to the end of said intermediate portion and projecting axially therefrom.

17. An angioplasty guidewire according to claim 16 wherein:

said intermediate portion further includes:

a locking mechanism for selectively inhibiting relative movement between said flexible member and stiffener to enhance rotational transmission between said proximal shaft and said distal tip.

18. An angioplasty guidewire according to claim 16 wherein:

said stiffener comprises a hypotube; and

said flexible member comprises a resilient core wire.

19. An angioplasty guidewire according to claim 18 wherein:

said core wire is fixed to said distal tip.

20. An angioplasty guidewire according to claim 19 wherein:

said hypotube includes a formed distal open end tapered radially inwardly; and

said core wire includes a medial tapered portion complementally formed to effect a friction fit through said formed passage and within said hypotube end to lock in said tapered end and define a locking mechanism.

21. An angioplasty guidewire according to claim 19 wherein:

said proximal shaft includes a formed passage;

said hypotube includes a formed distal open end tapered radially inwardly; and

said core wire includes a sawtooth wave-shaped diametrically offset portion formed to effect a continuous friction fit with said hypotube tapered end and define said clamping device.

22. An angioplasty guidewire according to claim 19 wherein:

said hypotube includes an interior surface formed into a polygonal cross-sectional shape; and

aid core wire is formed with a polygonal cross-section for close-fitting slidable axial receipt within said hypotube to prevent relative rotation between said hypotube and said core wire and provide enhanced torsional stiffness through said intermediate section.

23. An angioplasty guidewire according to claim 11 wherein:

said flexible portion comprises a formed hypotube having an interior bore closed at the distal extremity of said intermediate section; and

said stiffener comprises a relatively stiff wire.

24. An angioplasty guidewire according to claim 23 wherein:

said hypotube is fixed; and

said core wire is moveable within said internal bore.

25. An angioplasty guidewire according to claim 23 wherein:

said internal bore is of a constant diameter; and

said core wire is of a constant diameter.

26. An angioplasty guidewire comprising:

a proximal shaft having a distal end;

an intermediate section extending axially outwardly from said shaft to a distal joint and including a hypotube having a formed distal open end tapered radially inwardly to define a restricted mouth and a flexible core wire formed with a medial portion complementally formed to selectively engage said hypotube mouth and form a friction fit, said core wire slidably received in said hypotube and anchored to said distal joint, said hypotube operable to axially shift along said core wire and cooperatively impart a variable stiffening force on said intermediate section; and

a flexible distal tip mounted to said distal joint and projecting axially therefrom.

27. An angioplasty guidewire according to claim 26 wherein:

said medial portion is formed with a radially inwardly directed taper to engage said hypotube mouth.

28. An angioplasty guidewire according to claim 26 wherein:

said medial portion is formed with a sawtooth wave-shaped diametrically offset portion formed to engage said hypotube mouth.

29. An angioplasty guidewire comprising:

a proximal shaft;

an intermediate section; and

a flexible distal tip joined to the intermediate section at a distal joint, wherein the intermediate section comprises a tapered tubular member having an interior bore closed at the distal extremity of the intermediate section, and a moveable stiffening member within said internal bore.

30. An angioplasty guidewire according to claim 29 wherein:

said internal bore is formed with a relatively constant diameter.

31. An angioplasty guidewire according to claim 29 wherein:

said moveable stiffening member comprises an untapered core wire.

32. An angioplasty catheter system comprising:

an angioplasty catheter having an expandable element for dilating radially outwardly inside a blood vessel; and

a controllably variable guidewire including a proximal shaft;

an intermediate section extending longitudinally from said shaft to a distal joint and including a stiffener and a flexible member, said stiffener and flexible member disposed in coaxial slidable relationship and operable, as said stiffener and flexible member undergo relative axial shifting, to cooperatively impart a variable stiffening force on said intermediate section; and

a flexible distal tip mounted to the end of said intermediate portion and projecting axially therefrom.

33. An angioplasty catheter system according to claim 32 wherein:
said expandable element comprises a stent.

34. An angioplasty catheter system according to claim 32 wherein:
said expandable element comprises a balloon.

35. A method of deploying a guidewire through a vasculature to a restricted location in a blood vessel, said guidewire including an intermediate section comprising a flexible member and a stiffener coaxially disposed slidably with said flexible member, said method including the steps of:
shifting said flexible member and stiffener into an initial position of said guidewire to effect a predetermined flexibility in said intermediate section;
inserting said guidewire through an incision accessing said vasculature;
threading said guidewire through said vasculature to said restricted location; and
stiffening said intermediate section by axially displacing said stiffener with respect to said flexible member sufficient to support a dilation catheter.

36. A method of deploying a guidewire according to claim 35 wherein said threading step includes:
locking said flexible member and stiffener to inhibit relative rotation therebetween and increase the torsional stiffness of said guidewire.

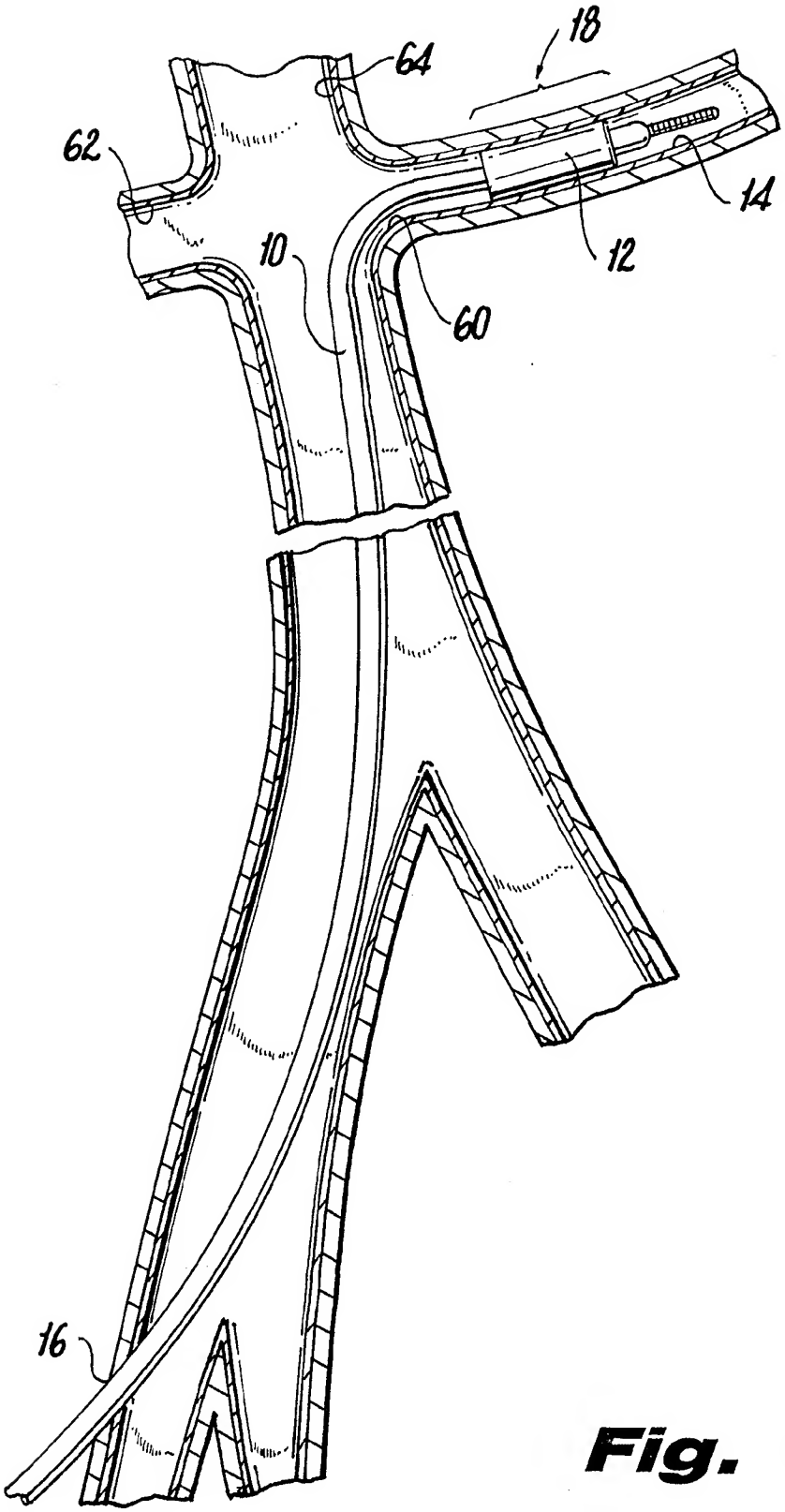


Fig. 1

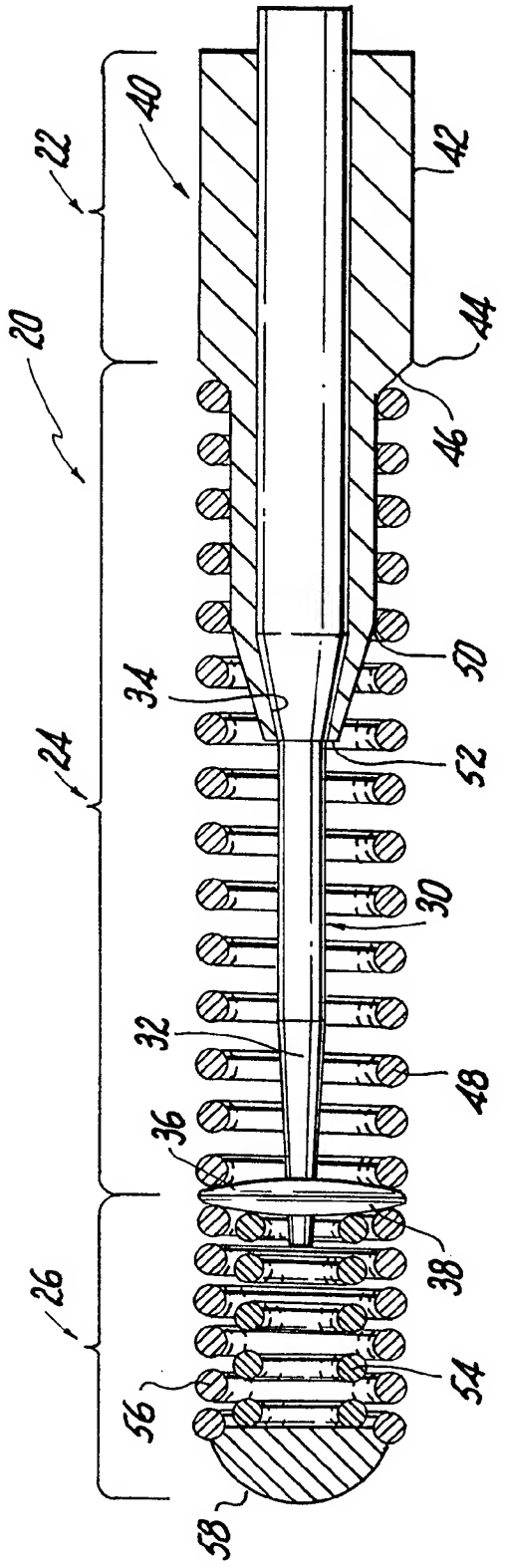


Fig. 2

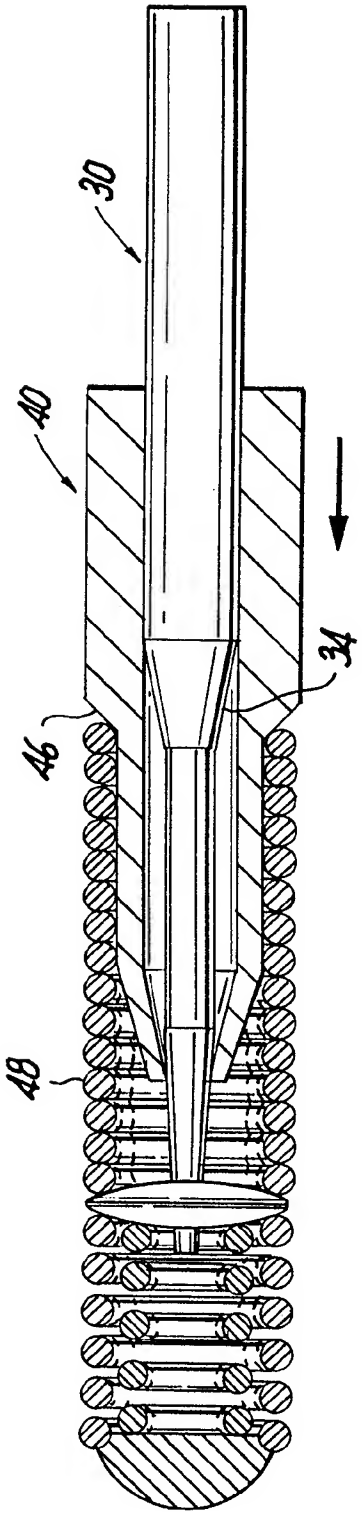


Fig. 3

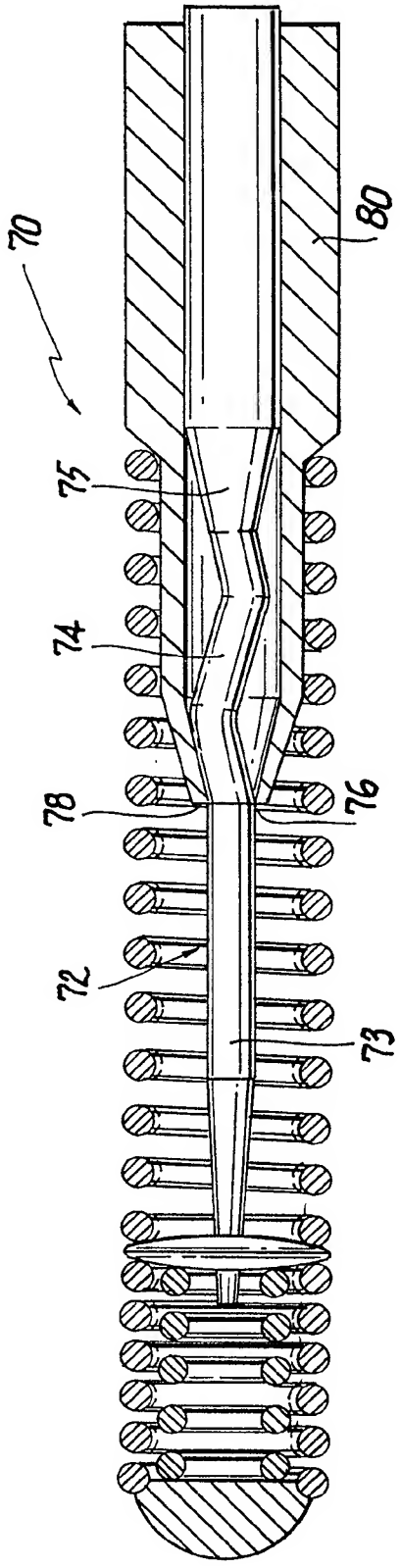


Fig. 4

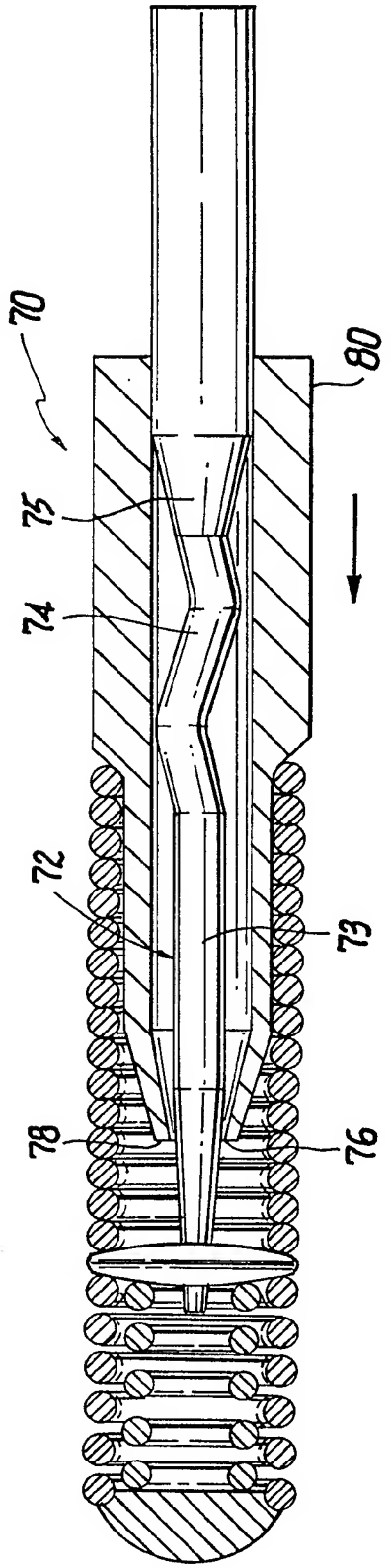


Fig. 5

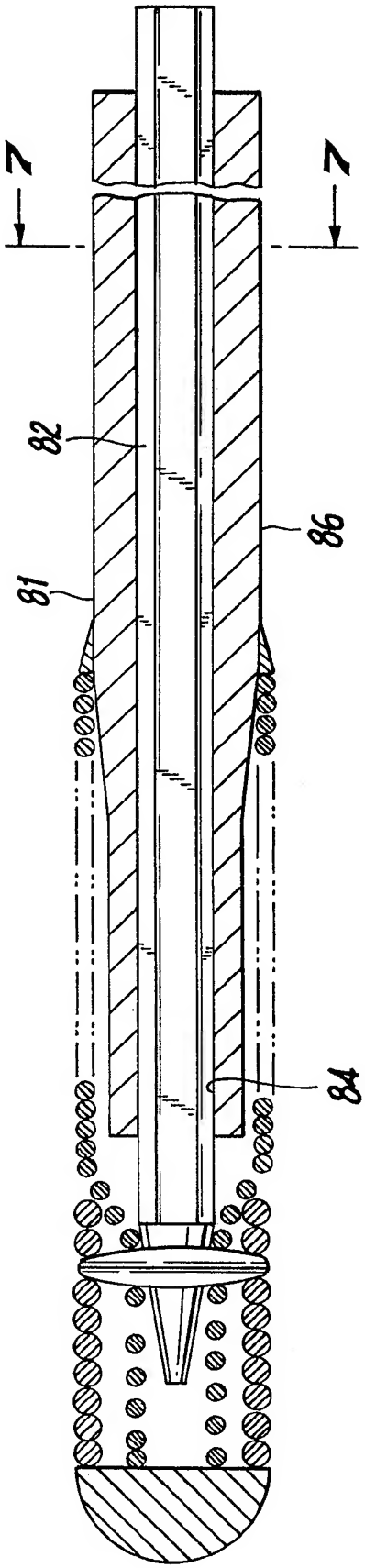
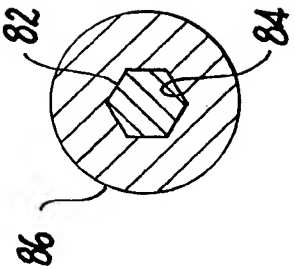


Fig. 6



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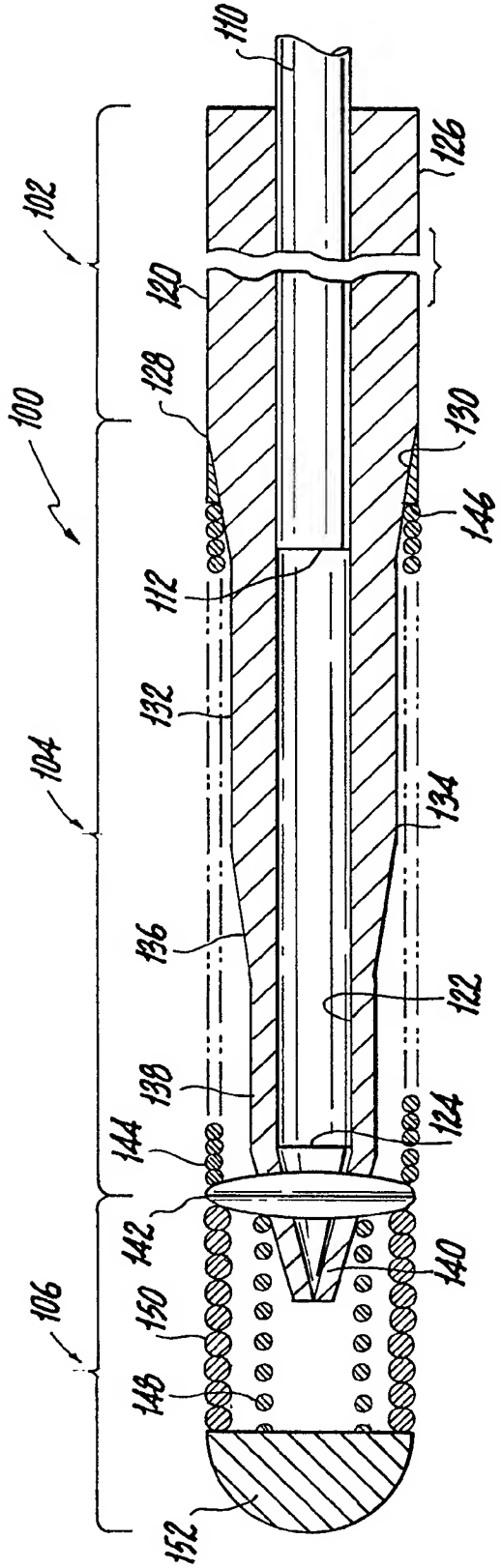
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Fig. 8

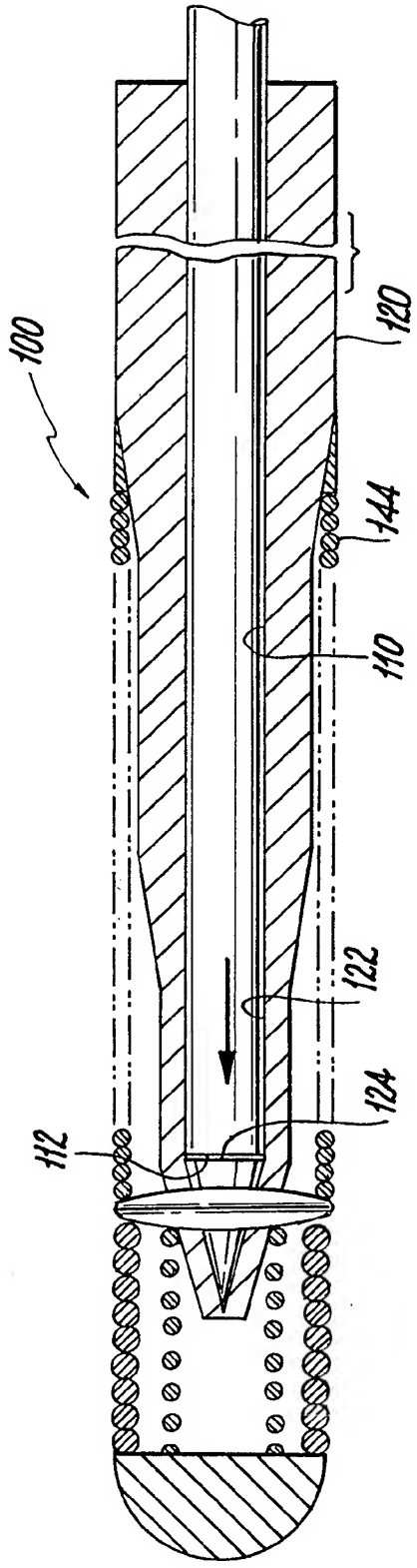
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Fig. 9

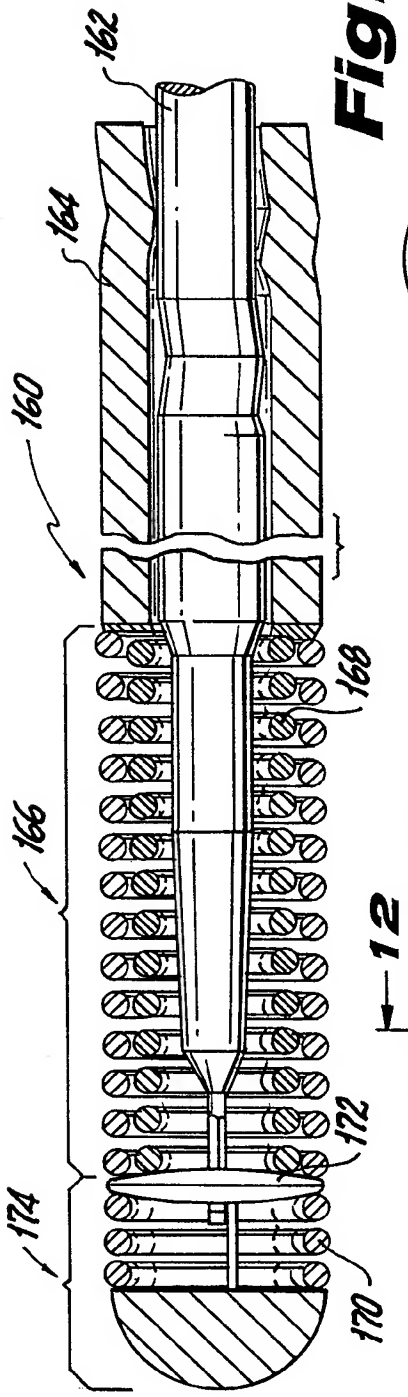

Fig. 10

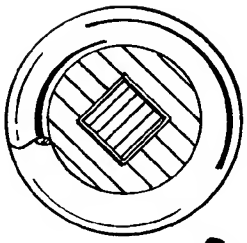

Fig. 12

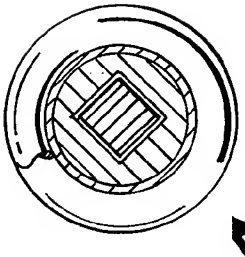

Fig. 14

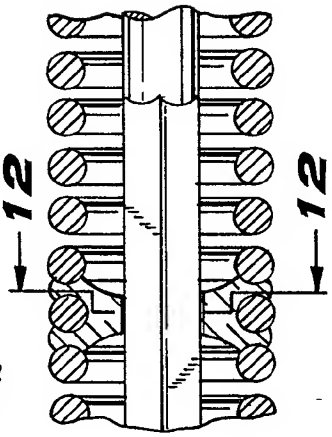

Fig. 11

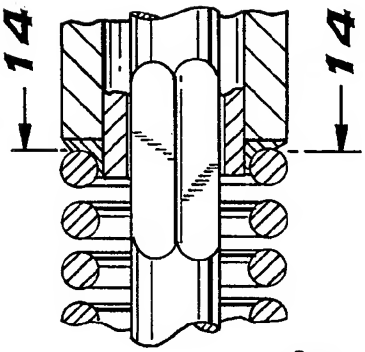

Fig. 13

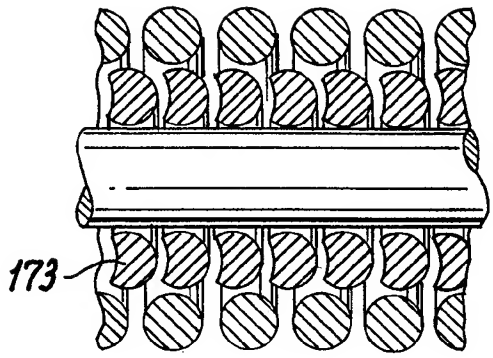

Fig. 15

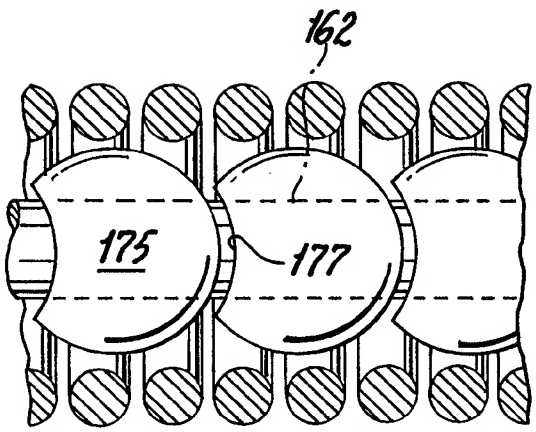

Fig. 16

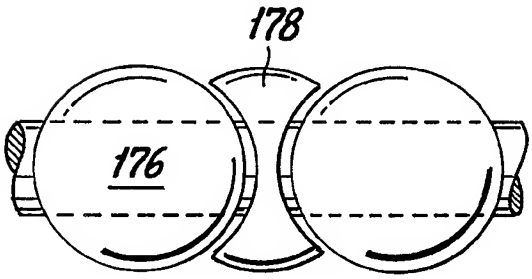

Fig. 17

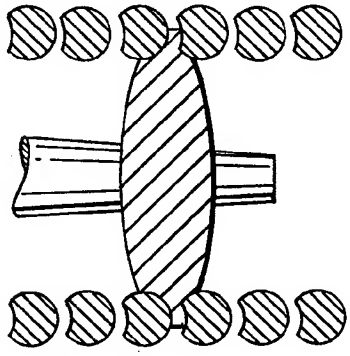

Fig. 18

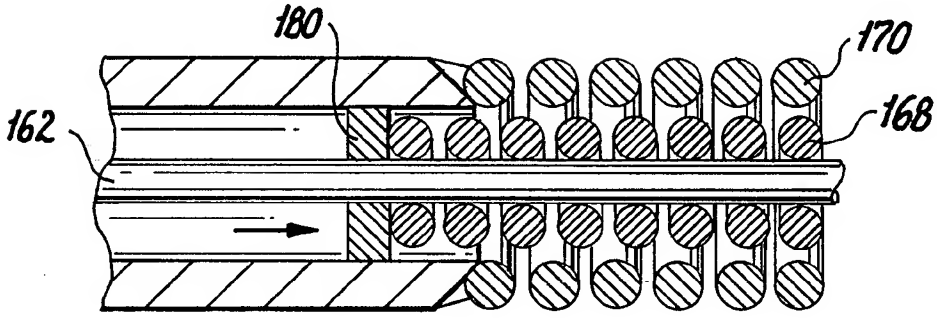

Fig. 19

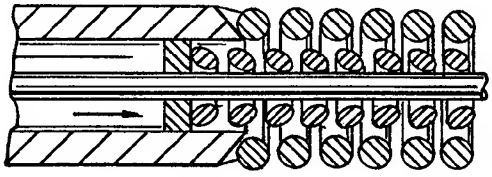

Fig. 20

INTERNATIONAL SEARCH REPORT

Int ..tional Application No
PCT/US 98/13251

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M25/01

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 605 162 A (MIRZAEE) 25 February 1997	1,3,4,6, 11,13, 16,18, 19, 23-25, 32,34
A	see the whole document	26,29,30
A	US 4 215 703 A (WILLSON) 5 August 1980	1,3,11, 16,18, 26,29,32
	see abstract; figures	
A	EP 0 750 879 A (SCHNEIDER) 2 January 1997	1,16,26, 29
	see claim 1; figures	
	-/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
15 October 1998	26/10/1998

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Kousouretas, I

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Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Int. ational Application No
PCT/US 98/13251

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 372 144 A (MORTIER) 13 December 1994 see column 18, line 3 - line 68; figures	1,8
P,X	EP 0 812 600 A (CORDIS) 17 December 1997	1,3,16, 18,19, 23-25
P,A	see the whole document	26,29
P,A	WO 98 04189 A (THE NEMOURS FOUNDATION) 5 February 1998 see abstract; figures	1,8

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Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 98/13251

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 14,15,35,36
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery.

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int tional Application No
PCT/US 98/13251

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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